K080934

MAY 28 2008

Nucletron

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Department of Health and Human Services
Centre of Device and Radiological Health
Office of Device Evaluation
Special 510(k) section

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

As required by section 807.92(c)

Submitter of 510(k):

Company name:	Nucletron Corporation
Registration number:	1121753
Address:	8671 Robert Fulton Drive Columbia, MD 21046
Phone:	410-312-4100
Fax:	410-312-4198
Correspondent:	Lisa Dimmick Director Assurance & Regulatory Affairs

Modified Device Name:

Trade/Proprietary Name:	Vienna Ring CT/MR Applicator
Common/Usual Name:	JAQ, Remote controlled radionuclide applicator system
Classification Name:	90 (Radiology)
Classification:	21CFR892.5700 Class II

Legally Marketed Device(s)
Our device is substantially equivalent to the legally marketed predicate device cited in the table below:

Manufacturer	Device	510(k) #
Nucletron BV	Ring Applicator Set	K953946

Description:

The Vienna Ring CT/MR Applicator is based on the Ring CT/MR Applicator Set enhanced with the addition of nine guide holes in the ring tube (seven holes for part number 189.699). These guide holes allow placement of interstitial titanium needles using the ring tube as a needle template while still maintaining the treatment channel of the ring tube. The addition of interstitial needles makes it possible to achieve asymmetric alteration of the dose distribution. The needles are inserted perpendicular to the ring and are parallel to the tandem. The

applicator is fully CT/MR compatible. Its design uses composite fiber tubing, to eliminate distortion on CT or MR imaging. Interstitial needles can be used for treatment of carcinoma where no lumen or cavity is available. The Titanium Needles are fully CT/MR compatible and can be used in order to have minimal artifacts on the acquired images.

The device is the same as the legally marketed predicate device cited. The only change is that the applicator allows placement of pre-bent Titanium Needle Sets which are based on the predicate stainless steel Interstitial Needle Sets (K953946).

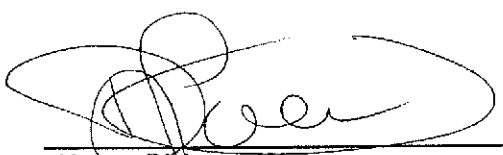
Intended use:

The modified device has the same intended use as the legally marketed predicate device cited:

The Vienna Ring CT/MR Applicator is intended for use with Nucletron remote afterloading equipment for gynaecological brachytherapy procedures

Summary of technological considerations:

The Vienna Ring CT/MR Applicator is substantially equivalent to the cleared predicate device, Ring CT/MR Applicator Set, 510(k)#: K953946. The Titanium Needle Sets the Vienna Ring CT/MR Applicator is compatible with are substantial equivalent to the Interstitial Needles Setst, 510(k)#: K953946.



01-04-2008

Name: Dick van Waes
Title: Vice President
Nucletron B.V.
Veenendaal, The Netherlands

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 28 2008

Ms. Lisa Dimmick
Director Regulatory Affairs
Nucletron Corporation
8671 Robert Fulton Drive
COLUMBIA MD 21046-2133

Re: K080934
Trade/Device Name: Vienna Ring CT/MR Applicator
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radio-nuclide applicator system
Regulatory Class: II
Product Code: JAQ
Dated: April 2, 2008
Received: April 2, 2008

Dear Ms. Dimmick:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number	K080934
Device Name	Vienna Ring CT/MR Applicator
Indications for Use	The Vienna Ring CT/MR Applicator is intended for use with Nucletron remote afterloading equipment for gynaecological brachytherapy procedures.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K080934